UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,273	01/18/2005	Robert P Schnall	28657	7217

7590 08/23/2007

Martin Moynihan
Anthony Castorina
Suite 207
2001 Jefferson Davis Highway
Arlington, VA 22202

EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
08/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,273	SCHNALL, ROBERT P	
	Examiner	Art Unit	
	Patricia C. Mallari	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/30/07.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 and 3-62 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,3,4,6,8,10-16,18,20,21,23-31,33-41,44,47,49-52,57,58 and 62 is/are rejected.

7)☒ Claim(s) 5,7,9,17,19,22,32,42,43,45,46,48,53-56,59-61 and 63 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 18 January 2005 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is a non-final Office action. The allowability of claim 47 has been regretfully withdrawn. See the rejection below for details.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the adhesive layer on the surface of the base facing the pressure applicator and sensor claimed in claim 11 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claim 11 recites, "base includes an adhesive layer on its surface facing the pressure applicator and sensor for adhering the base to the subject's skin". However, the application lacks sufficient antecedent basis for the adhesive layer on the base facing the pressure applicator and sensor. Figures 1b, 2b, 3b, and 4b, show the adhesive layer 14, 24, 34, 44, but the adhesive layer does not, in the figures, appear to be facing the pressure applicator 12, 22, 32, 42 or the sensor 13, 23, 33, 43.

Claim 35 recites, "said probe is applied to a relatively restricted area of the subject's skin which is relatively rich in arteriovenous anastomoses vessels". Claim 36 recites, "said probe is applied to a relatively restricted area of the subject's skin which is relatively poor in arteriovenous anastomoses vessels". The instant specification lacks sufficient antecedent basis for the placement of the probe on an area of the skin that is either rich or poor in "arteriovenous anastomoses vessels" as claimed in claims 35 and 36.

Claim 38 recites, "said probe is applied to a relatively restricted area of the subject's skin on the subject's forearm". The specification lacks sufficient antecedent basis for the placement of the probe on the forearm as claimed in claim 38.

Claim 49 recites, "wherein the sensing modality for sensing changes in the pulsatile arterial blood volume at said measurement site is the pressure change within the said pressure applicator". The instant specification lacks sufficient antecedent basis for this limitation.

Claim Objections

Claims 26-28, 30, 47, and 49 are objected to because of the following informalities:

Claims 26-28 and 30 recite the term "respectively" but do not specify to what the claimed characteristic is respective to. It appears that each claimed characteristic connected with the term "respectively" refers to a characteristic of a particular probe. It is recommended that the applicants refer to the probes as "first probe" and "second probe" and further that the applicants specify the characteristics of the probes using the language "first probe" and "second probe" rather than using the term "respectively". Alternatively, the term should be deleted.

On line 2 of claim 47, "anelectrode" was replaced with "an electrode".

On line 3 of claim 49, "the said" should be replaced with "said".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 10, 18, 20, 33-36, 39, 50, 52, and 62 are rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by US Patent Application Publication No. 2002/0026121 to Kan. Kan teaches a probe for application to a selected area of a subject's skin covering a body part, the selected area serving as a measurement site for measuring changes in the pulsatile arterial blood volume thereat, comprising a base 5 for application to the selected area of the subject's skin at a measurement site, a pressure applicator 3 carried by the base for applying a static pressure to the skin at the measurement site when the base is applied thereto, and a sensor 4 carried by the pressure applicator 3 for sensing changes in the pulsatile arterial blood volume at the measurement site when the base is applied thereto (see entire document, especially figs. 1-3; paragraphs 30-32, and 44-47 of Kan). The pressure applicator is designed to apply to the measurement site a static pressure of sufficient magnitude to partially unload the tension of, but not to occlude, the arteries at the measurement site, when the base is applied thereto. The pressure applicator is also configured to substantially

prevent venous distention and blood pooling at the measurement site by applying sufficient external counter pressure to effectively collapse the underlying veins and limit the local venous blood flow to the arterial throughput while permitting free venous drainage with respect to the measurement site through tissues surrounding the measurement site. The pressure applicator is configured to apply the static pressure to a relatively restricted part of the subject's skin, which area does not completely encircle the body part at the measurement site and occupies a relatively small fraction of the surface perimeter of the respective body part at the measurement site, to thereby permit free venous drainage from the measurement site via a wide region of the unrestricted passageways surrounding the measurement site (see entire document, especially figs. 1 and 3; paragraphs 30 and 31 of Kan). The applicant discloses in the instant application that applying a pressure above normal venous pressure but below the diastolic arterial blood pressure to an area of the body part that does not extend the entire perimeter of the body part would accomplish the features set forth in the previous three sentences describing the pressure applicator (see line 24 of p. 9- line 6 of p. 10; lines 16-24 of p. 10; lines 9-18 of p. 14 of the instant application). The pressure applicator of Kan is capable of applying a pressure that is within a range from lower than the possible mean pressure of the subject to higher than the possible systolic blood pressure, which range would include a pressure above normal venous pressure but below the diastolic arterial blood pressure. Furthermore, the pressure applicator applies the pressure to an area of the body part that does not extend the entire

perimeter of the body part (see entire document, especially figs. 1, 3; paragraphs 30, 31 of Kan).

Regarding claim 4, the pressure applicator comprises a fluid chamber 3 and an external source of fluid for applying the static pressure to the measurement site (see entire document, especially fig. 1; paragraph 53 of Kan).

Regarding claim 10 the base 5 is of a relatively non-stretchable material and carries the pressure applicator and sensor at the center thereof (see entire document, especially figs. 1-4; paragraph 47 of Kan).

Regarding claims 18 and 33, Kan further teaches an apparatus for detecting and indicating a medical condition or change in physiological state of a subject comprising a probe as described above with regard to claim 1, and a data processor system 29, 31 for utilizing said measured changes to detect and indicate a medical condition or change in physiological state of the subject (see entire document, especially fig. 1; paragraphs 54-56 of Kan). Additionally, Kan describes using such a probe and processor to detect and indicate a medical condition or change in physiological state of a subject (see entire document, especially paragraphs 52-56 of Kan).

Regarding claim 20, the data processor system utilizes the measured changes in pulsatile arterial volume to indicate changes in the systemic blood pressure of the subject (see entire document, especially paragraph 54 of Kan).

Regarding claim 34, the probe is applied to a relatively restricted area of the subject's skin substantially overlying a medium to large sized artery (see entire document, especially figs. 1 & 3 of Kan).

Regarding claim 35, the probe is applied to a relatively restricted area of the subject's skin that is relatively rich in arteriovenous anastomoses (see entire document, especially fig. 1 of Kan), relative, for example, to the skin of the thorax or abdomen.

Regarding claim 36, the probe is applied to a relatively restricted area of the subject's skin that is relatively poor in arteriovenous anastomoses vessels (see entire document, especially fig1 of Kan), relative, for example, to the palmar aspect of the distal phalanx.

Regarding claim 39, the probe is applied to a relatively restricted area of the subject's skin at the subject's wrist (see entire document, especially fig. 1 of Kan).

Regarding claim 51, a multiplicity of different sensors is used for sensing changes in the pulsatile arterial blood volume at said measurement site (see entire document, especially figs. 3 & 4; paragraphs 46, 53, 60 of Kan).

Regarding claim 52, the probe is applied over a skin region overlying a superficial conducting artery for deriving a signal for biofeedback input (see entire document, especially figs. 1 & 3; paragraphs 30, 43 of Kan). As to the language "for biofeedback input", the applicants should note that this is merely "intended use" language reciting an intended use of the signal derived from the probe. This language cannot be relied upon to define over the prior art, since Kan teaches all of the claimed steps and their recited relationships. The signal derived from the probe could most certainly be used "for biofeedback input" as claimed.

Regarding claim 62, the pressure applied by the pressure applicator extends in area beyond the region of the sensor (see entire document, especially figs. 1, 3, and 4

of Kan), such that the effective boundary of the pressure field overlying the sensing region is extended beyond the sensor itself. The pressure is applied to a region that does not completely encircle the body part and occupies a relatively small fraction of the surface perimeter of the respective body part at the measurement site, thereby substantially preventing venous distention and blood pooling at said measurement site and extended effective boundary of the pressure field by applying sufficient external counter pressure to effectively collapse the underlying veins and limit the local venous blood flow to the arterial throughput while permitting free venous drainage with respect to said measurement site through tissues surrounding said measurement site.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 6, 8, 10, 11, 18, 20, 33, 35-37, 49, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,230,342 to Bobo, Jr. et al. in view of US Patent No. 4,896,676 to Sasaki et al. Bobo, Jr. teaches a probe for application to a selected area of a subject's skin covering a body part, which area serves as a measurement site for measuring changes in the pulsatile arterial blood volume thereat. The probe comprises a base 19, 20 for application to the selected

area, a pressure applicator 18 carried by the base for applying a static pressure to the subject's skin at the measurement site when the base is applied thereto, and a sensor for sensing changes in the pulsatile arterial blood volume at the measurement site when the base is applied thereto (see entire document, especially figs. 1-3; col. 3, line 54-col. 4, line 31 of Bobo, Jr.) The applicants disclose applying a static pressure of between venous pressure and diastolic pressure to the site as applying a static pressure of sufficient magnitude to partially unload the wall tension of but not to occlude the arteries at the measurement site, and applying sufficient external counter pressure to effectively collapse the underlying veins and limit the local venous blood flow to the arterial throughput while permitting free venous drainage with respect to the measurement site through tissues surrounding the measurement site, thereby substantially preventing venous distention and blood pooling at the measurement site. The pressure applicator is capable of applying such a static pressure (see entire document, especially col. 4, lines 9-30 of Bobo, Jr.) The pressure applicator is also configured to apply the static pressure to a relatively restricted area of the subject's skin, which area does not completely encircle the body part at the measurement site and occupies a relatively small fraction of the surface perimeter of the respective body part at the measurement site (see entire document, especially fig. 3 of Bobo, Jr.) The applicants should note that the language "to thereby permit free venous drainage from the measurement site via a wide region of unrestricted passageways surrounding the measurement site" is merely "results language" describing the results of the pressure applicator applying the static structure as described. This results language cannot be relied upon to define over the

prior art, since Bobo, Jr. teaches all of the claimed structural features and their recited relationships. It is further noted that, since Bobo, Jr. is configured to apply the static structure as claimed, if Bobo, Jr. does not achieve the recited results, then the applicants have omitted an essential feature of the claimed invention (i.e. a problem under 35 U.S.C. 112, 1st paragraph). Bobo, Jr. lacks the sensor being carried by the pressure applicator.

However, Sasaki teaches a probe having a pressure applicator and a sensor, wherein the sensor 14A is carried by the pressure applicator (see entire document, especially fig. 2; col. 3, lines 12-47 of Sasaki). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have the pressure applicator of Bobo, Jr. carry the sensor, as shown in Sasaki, as it would merely be the substitution of one known sensor and applicator configuration for another, wherein the location of the sensor does not affect operation of the invention as a whole, and the combination would merely produce the predictable result of allowing a blood pressure measurement.

Regarding claim 4, the pressure applicator comprises a fluid chamber an external source of fluid for applying the static pressure to the measurement site (see entire document, especially figs. 1 & 4; col. 4, lines 9-30 of Bobo, Jr.)

Regarding claim 6, the pressure applicator comprises a chamber including a spring therein for applying a static pressure to said measurement site (see entire document, especially col. 3, lines 64-67 of Bobo, Jr.)

Regarding claim 8, the pressure applicator comprises a resilient, elastomeric material (see entire document, especially figs. 1 and 3; col. 5, lines 33-52 of Bobo, Jr.)

Regarding claim 10, the base 19 is of a relatively non-stretchable material (see entire document, especially col. 3, lines 55-60 of Bobo, Jr.), in comparison to a more stretchable material.

Regarding claim 11, the base includes an adhesive layer 22 on its surface facing the pressure applicator and sensor for adhering the base to the subject's skin (see entire document, especially fig. 2; col. 3, lines 59-62 of Bobo, Jr.)

Regarding claims 18 and 20, a data processor system 28 utilizes the measured changes to detect and indicate a medical condition, change in physiological state, and/or systemic blood pressure (see entire document, especially co. 4, lines 18-22 of Bobo, Jr.)

Regarding claim 33, the probe is applied to a measurement site on the subject's skin for measuring changes in the pulsatile blood volume and the measured changes are utilized to detect and indicate a medical condition or change in physiological state (see entire document, especially col. 3, lines 37-67; col. 4, lines 9-30 of Bobo, Jr.)

Regarding claims 35 and 36, the probe is applied to a relatively restricted area of the subject's skin which is relatively rich or poor in arteriovenous anastomoses vessels, compared to other sites of the body.

Regarding claim 37, the probe is applied to a relatively restricted area of the subject's skin on the forehead (see entire document, especially fig. 3 of Bobo, Jr.)

Regarding claim 49, the sensing modality for sensing changes in the pulsatile arterial blood volume at the measurement site is the pressure change within the pressure applicator (see entire document, especially col. 4, lines 9-30 of Bobo, Jr.)

Regarding claim 51, the probe is applied over a skin region predominantly containing microvascular blood vessels for deriving a signal (see entire document, especially fig. 2 of Bobo, Jr.). As to the language "for biofeedback input", the applicants should note that this is merely "intended use" language describing the intended use of the derived signal. This language cannot be relied upon to define over the prior art, since Bobo, Jr., as modified, teaches all of the claimed method steps and their recited relationships. The signal acquired by Bobo, Jr., as modified, is certainly capable of use as a biofeedback input, as claimed.

Claims 1, 4, 10, 18, 24-31, 33-36, 39, 44, 50, 52, 57, 58, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,743,856 to Oka et al. in view of Kan. Oka teaches an apparatus comprising at least two probes constructed for application to at least two measurement sites at a known distance from each other. The probes detect pulse waves. A data processor system utilizes the outputs of the probes to indicate the pulse propagation velocity and to indicate the medical condition or change in physiological state of the subject (see entire document, especially figs. 2, 4, 5; col. 11, line 58-col. 12, line 60; col. 13, line 8-col. 14, line 67 of Oka). Oka lacks a probe according to claim 1 of the instant application. However, Kan, as described above, teaches a probe according to claim 1, wherein such a probe is capable of detecting features of a pulse wave. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the probe of Kan as that in Oka, as it would merely be the substitution of one known

pulse wave sensor for another, to achieve the predictable result of detecting the pulse wave of a subject to determine the pulse wave velocity.

Regarding claim 4, the pressure applicator comprises a fluid chamber 3 and an external source of fluid for applying the static pressure to the measurement site (see entire document, especially fig. 1; paragraph 53 of Kan).

Regarding claim 10 the base 5 is of a relatively non-stretchable material and carries the pressure applicator and sensor at the center thereof (see entire document, especially figs. 1-4; paragraph 47 of Kan).

Regarding claims 18 and 24, the combination as described above comprises two probes according to claim 1 and a data processor system utilizing the measured changes of both probes to detect and indicate the medical condition and/or change in physiological state.

Regarding claims 25-30, the probes are constructed for application to measurement sites in which the vascular beds thereat have different levels of autonomic nervous system activity or responsiveness, are mainly comprised of conduit arteries and microcirculatory vascular beds "respectively", are "respectively" predominantly affected by autonomic nervous system activity or by the level of systemic blood pressure, or are "respectively" predominantly affected by unequal levels of autonomic nervous system activity (see entire document, especially figs. 1-4 of Kan). As to the language "for application to measurement sites . . ." in each of claims 25-27, the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since Oka, as modified, teaches all of the

claimed structural limitations and their recited relationships. The probes of Oka, as modified, are certainly capable of such application to such sites, as claimed.

With further regard to claims 28-30, the data processor system compares the outputs of the probes to indicate the medical condition or change in physiological state of the subject (see entire document, especially col. 11, line 58-col. 12, line 60; col. 13, line 8-col. 14, line 67 of Oka).

Regarding claim 31, the probes are constructed for application to at least two measurement sites at a known distance from each other and the data processor utilizes outputs of each probe for indicating the pulse propagation velocity (see entire document, especially col. 11, line 58-col. 12, line 60; col. 13, line 8-col. 14, line 67 of Oka; figs. 1-3 of Kan).

Regarding claim 33, the combined references, as described above, further delineate a method wherein at least one probe is applied to a measurement site on the subject's skin for measuring changes in the pulsatile arterial blood volume thereat and the measured changes are utilized to detect and indicate a medical condition or change in physiological state of the subject (see entire document, especially col. 11, line 58-col. 12, line 60; col. 13, line 8-col. 14, line 67 of Oka; figs. 1-4; paragraphs 30-32, and 44-47 of Kan).

Regarding claim 34, the probe is applied to a relatively restricted area of the subject's skin substantially overlying a medium to large sized artery (see entire document, especially figs. 1 & 3 of Kan).

Regarding claim 35, the probe is applied to a relatively restricted area of the subject's skin that is relatively rich in arteriovenous anastomoses (see entire document, especially fig. 1 of Kan), relative, for example, to the skin of the thorax or abdomen.

Regarding claim 36, the probe is applied to a relatively restricted area of the subject's skin that is relatively poor in arteriovenous anastomoses vessels (see entire document, especially fig. 1 of Kan), relative, for example, to the palmar aspect of the distal phalanx.

Regarding claim 39, the probe is applied to a relatively restricted area of the subject's skin at the subject's wrist (see entire document, especially fig. 1 of Kan).

Regarding claim 44, at least one additional probe is applied to at least an additional measurement site on the subject's skin for measuring the pulsatile arterial blood volume thereat, the measurement of the additional probe being utilized for detecting and indicating the medical condition or change in physiological state of the subject (see entire document, especially col. 11, line 58-col. 12, line 60; col. 13, line 8-col. 14, line 67 of Oka).

Regarding claim 50 a multiplicity of different sensors are used for sensing changes in the pulsatile arterial blood volume at the measurement site (see entire document, especially figs. 3 & 4 of Kan).

Regarding claims 52 and 58, the probe(s) is/are applied over a skin region overlying a superficial conducting artery for deriving a signal for biofeedback input (see entire document, especially figs. 1 & 3; paragraphs 30, 43 of Kan). As to the language "for biofeedback input", the applicants should note that this is merely "intended use"

language reciting an intended use of the signal derived from the probe. This language cannot be relied upon to define over the prior art, since Oka, as modified, teaches all of the claimed steps and their recited relationships. The signal derived from the probe could most certainly be used "for biofeedback input" as claimed.

Regarding claim 57, a multiplicity of different sensors is used for detecting changes in the pulsatile arterial blood volume at the measurement sites (see entire document, especially figs. 3 & 4 of Kan).

Regarding claim 62, the pressure applied by the pressure applicator extends in area beyond the region of the sensor (see entire document, especially figs. 1, 3, and 4 of Kan), such that the effective boundary of the pressure field overlying the sensing region is extended beyond the sensor itself. The pressure is applied to a region that does not completely encircle the body part and occupies a relatively small fraction of the surface perimeter of the respective body part at the measurement site, thereby substantially preventing venous distention and blood pooling at said measurement site and extended effective boundary of the pressure field by applying sufficient external counter pressure to effectively collapse the underlying veins and limit the local venous blood flow to the arterial throughput while permitting free venous drainage with respect to said measurement site through tissues surrounding said measurement site.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kan, as applied to claims 1, 4, 10, 18, 20, 33-36, 39, 50, 52, 54, and 62 above, and further in view of US Patent No. 5,640,964 to Archibald et al. Kan is silent as to how the pressure

in the bladder is applied to the body. However, teaches a probe wherein the pressure applicator applies a starting pressure of, for example 20 mm Hg and increases the pressure from there until an optimal pressure is applied (see entire document, especially figs. 9-11; col. 15, line 49-col. 16, line 31 of Archibald), wherein a starting value of 20 mm Hg is a pressure above a subject's local venous pressure and below the subject's diastolic blood pressure. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the pressure sweeps of Archibald as that of Kan, since Kan teaches increasing the pressure of the pressure applicator, and Archibald discloses an appropriate method of doing so.

Claim 12, 21, 23, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kan, as applied to claims 1, 4, 10, 18, 20, 33-36, 39, 50, 52,54, and 62 above, and further in view of US Patent No. 3,412,729 to Smith, Jr. Kan lacks the probe also including an optical sensor for sensing the blood oxygen saturation level. Smith, Jr. teaches a probe comprising a pressure applicator and a sensor, the sensor being an optical sensor that determines blood pressure values, blood oxygenation values, and pulse rate values. All of the claimed component parts are known in the references Kan and Smith, Jr. The only difference is the combination of the "old elements" into a single device by incorporation into a single probe. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the blood oxygenation (oxygen saturation) and pulse rate functionality taught by Smith, Jr. into the probe of Kan, since Smith, Jr. shows that a blood pressure measuring device

that utilizes a pressure bladder and optical sensor can be combined in operation with the blood oxygenation and pulse rate functionalities, and that such combination would provide important data in connection with the determination of the well-being of a subject (see entire document, especially col. 1, lines 45-60 of Smith, Jr.)

Claims 12-16, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kan, as applied to claims 1, 4, 10, 18, 20, 33-36, 39, 50, 52, 54, and 62, above, and further in view of US Patent No. 6,516,289 to David. Kan lacks the probe including an optical sensor for sensing the blood oxygen saturation level, an electrode for sensing electrical potential, such as the ECG signal of the subject, or an acoustic sensor for sensing a sound signal of the subject. However, David discloses a probe comprising a blood pressure sensor 16, 18 in combination with a blood oxygenation sensor 36, ECG electrodes 30, and acoustic sensors (stethoscopes/microphones) 50, 52 (see entire document, especially figs. 2, 4, and 6; col. 3, lines 16-37; col. 4, lines 1-9 and lines 31-38; col. 5, lines 21-58; col. 6, lines 15-16 of David). All of the claimed component parts are known in the references of Kan and David. The only difference is the combination of the "old elements" into a single device by incorporation into a single probe. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the ECG electrodes, blood oxygen saturation sensor, and acoustic sensor of David into the probe of Kan, since the operation of the operation of the ECG electrodes, blood oxygen saturation sensor, and acoustic sensor is in no way dependent upon the operation of the operation of the blood pressure sensor, and these sensors can be used

in combination for the predictable results of providing simultaneous acquisition of important physiological data (see entire document, especially col. 1, lines 50-57 of David), wherein such data is, in particular, useful for the purpose of ambulatory telemedical follow-up of patients in their own environment and for reciprocal calibration and easy acquisition of important, integrated physiological data (see entire document, especially col. 2, lines 4-15 of David).

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kan, as applied to claims 1, 4, 10, 18, 20, 33-36, 39, 50, 52, 54, and 62 above, and further in view of US Patent No. 6,516,289 to David. Kan teaches measuring blood pressure using a probe, but lacks applying the probe to the forearm of the subject. A person of ordinary skill in the art, upon reading Kan, would recognize the capability of measuring blood pressure from an alternate site. David teaches measuring blood pressure from a forearm, among other locations, of a subject (see entire document, especially col. 3, lines 18-20 of David). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the probe of Kan to a forearm to measure blood pressure because a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp, and wherein such a combination would merely produce the predictable result of measuring blood pressure.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kan, as applied to claims 1, 4, 10, 18, 20, 33-36, 39, 50, 52, 54, and 62 above, and further in

view of US Patent No. 6,162,181 to Hynson et al. Kan lacks applying the probe to the palm of the hand or sole of the foot. However, Hynson discloses determining blood pressure by applying a probe on the palm of a user's hand to detect pulsatile arterial blood volume changes in the palmar arch (see entire document, especially col. 2, lines 23-36; col. 4, lines 1-15 of Hynson). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the probe of Kan to the palm of a subject's hand in order to minimize patient discomfort, acquire stronger oscillations, and minimize finger vasoconstriction problems (see entire document, especially col. 2, lines 41-67 of Hynson), and further because a person with ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.

Claim 47 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Oka in view of Kan, as applied to claims 1, 4, 10, 18, 24-31, 33-36, 39, 44, 50, 52, 57, 58, and 62 above, and further in view of David. Oka, as modified, lacks at least two of the probes including an ECG electrode. However, David teaches a blood pressure measuring probe 18 comprising an ECG electrode 30 (see entire document, especially figs. 2, 3; col. 3, lines 16-36 of David). Therefore, it would have been obvious to one of ordinary skill in the art to combine an ECG electrode with the probe of Oka, as modified, wherein such a combination is shown in David and would be useful for integration of sensors for the simultaneous acquisition of other important physiological data, for the simultaneous recording, storage, and transmission of data without the need for difficult manipulations, and for reciprocal calibration and easy acquisition of important,

integrated physiological data (see entire document, especially col. 1, lines 51-57; col. 2, lines 4-11 of David).

Response to Arguments

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 5, 7, 9, 17, 19, 22, 32, 42, 43, 45, 46, 48, 53-56, 59-61, and 63ected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 5, the primary reason for allowance is the inclusion of the chamber having at least one elastic wall constructed to utilize Laplace's law and including a self-contained fluid for applying the static pressure to the measurement site such that the level of applied pressure is substantially unaffected by the mechanical characteristics of the underlying tissues, in combination with all of the other limitations of the claim.

Regarding claim 9, the primary reason for allowance is the inclusion of the resilient elastomeric material being of a relatively large uncompressed length such that the effective pressure generated by it, when it is compressed, is substantially unaffected by relatively small variations in compressed length due to the mechanical characteristics of the underlying tissues, in combination with all of the other limitations of the claim.

Regarding claim 17, the primary reason for allowance is the inclusion of the clamping device for applying a clamping force to the base of the probe when applied to the measurement site, and a counter-force to the respective body part of the subject at the opposite site of the measurement site, in combination with all of the other limitations of the claims.

Regarding claims 19 and 22, the primary reason for allowance is the inclusion of the processor system utilizing the measured changes in pulsatile arterial volume to indicate the peripheral arterial tone or the vascular tone of the subject, in combination with all of the other limitations of the claims.

Regarding claim 32, the primary reason for allowance is the inclusion of the data processor system utilizing said measured changes in the pulsatile arterial blood volume and the ECG signal to determine the pulse transit time and/or the pulse propagation velocity, wherein "said measured changes" includes changes measured by both the probe according to claim 1 (see claim18) and the one additional probe according to claim 1 (see claim 24), in combination with all of the other limitations of the claims.

Regarding claims 42 and 43, the primary reason for allowance is the inclusion of the probe being applied over a superficial artery or skin region predominantly containing

microvascular blood vessels for evaluating an endothelial function of the subject, in combination with all of the other limitations of the claims.

Regarding claims 45 and 46, the primary reason for allowance is the inclusion of the probes being applied to measurement sites in which the vascular beds thereat have different levels of reactivity to autonomic stimulation or different responses to reflex eliciting events, in combination with all of the other limitations of the claims.

Regarding claim 48, the primary reason for allowance is the probe being applied to the subject's body surface overlying a superficial conducting artier and another of the probes is applied to a subject's body surface overlying a predominantly microcirculatory vascular bed, in combination with all of the other limitations of the claim.

Regarding claims 53, 54, and 59, the primary reason for allowance is the probe being applied over a skin region predominantly containing microvascular blood vessels or overlying a superficial conducting artery for deriving a signal in response to a physical, pharmacological agent or mental stressor, in combination with all of the other limitations of the claims.

Regarding claims 55, 56, 60, and 61, the primary reason for allowance is the inclusion of detecting comprising viewing time-course or variations in a peripheral arterial tone signal, in combination with all of the other limitations of the claims.

Regarding claim 63, the primary reason for allowance is the inclusion of the sleep/wake detector, wherein the data processor system utilizes the measured changes to indicate the sleep/wake status of the subject, in combination with all of the other limitations of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/pcm/

ROBERT L. NASSER
PRIMARY EXAMINER